PSJ3

Exhibit 639

BuzzeoPDMA
Now Part of IMS Health

Via Email: Robert.Brown@andanet.com

November 12, 2015

Robert I. Brown, Director
Regulatory Compliance, ANDA
2915 Weston Road,
Weston, FL 33331

Dear Mr. Brown:

Please find attached a report regarding a Suspicious Order Monitoring (SOM) Assessment conducted at ANDA by BuzzeoPDMA Consulting Manager, Robert Williamson and IMS Health Statistician Michael Liu on October 20 and 21, 2015. The review included ANDA's due diligence programs, SOM SOPs, discussions relating to order calculations and interviews with staff regarding the firm's corporate interaction with the Drug Enforcement Administration (DEA). Consultants identified weaknesses in the order entry process. Additional recommendations are offered in terms of industry "best practices" and BuzzeoPDMA experience with clients.

Please let me know if you need clarification on any issues. Also, please feel free to contact Manager Williamson regarding the report or any other controlled substance questions or consulting needs.

Sincerely,

Ronald W. Buzzeo
Ronald W. Buzzeo, R.Ph.
Chief Regulatory Officer

BuzzeoPDMA
Now Part of IMS Health

ANDA Incorporated
2915 Weston Road
Weston Florida

SUSPICIOUS ORDER MONITORING ASSESSMENT

INTRODUCTION

On September 17, 2015, BuzzeoPDMA Now Part of IMS Health entered into an agreement with Actavis to conduct a Suspicious Order Monitoring (SOM) Assessment of ANDA's SOM compliance program. The intent of the project was to provide recommendations for enhancing ANDA's SOM model. Included in the review as described in the agreement were SOM items such as new and ongoing customer "due diligence" activities, corporate SOM procedures, SOM order entry procedures, including SOM modeling techniques, order investigation and clearing, and reporting practices.

On October 20 and 21, 2015, Robert C. Williamson, Manager, DEA Consulting, BuzzeoPDMA and Michael Liu, Statistician, IMS Health, visited ANDA at the firm's corporate headquarters in Weston, Florida. Robert Brown the Director of Regulatory Affairs at ANDA was the lead point of contact for the review. Director Brown provided background information, including SOM procedures for the review and organized a series of meetings with ANDA's SOM staff to allow consultants to observe SOM procedures at ANDA "first hand." Tom Napoli, CPP, Associate Director, Actavis, Controlled Substance Compliance was also present as an observer. Michael Cochrane, Executive Director, Regulatory Compliance, ANDA, provided Consultants with corporate SOM background information and was involved with portions of the review. There was an opening and closing meeting with the aforementioned individuals and Charles Phillips, President.

ANDA is a "secondary" drug wholesaler, meaning that most of their customers purchase controlled substances from other suppliers and order from ANDA when they cannot purchase from their "primary" suppliers. Secondary suppliers have DEA SOM challenges since they do not have a history of interactions with customers or their interaction is sporadic. The firm is the primary supplier for Publix and the sole secondary supplier for Walgreens.

As noted, the Weston distribution facility is the corporate headquarters. ANDA management reported that the firm also has distribution facilities in Groveport, Ohio and Olive Branch, Mississippi. There are approximately 750 employees, corporate wide. According to Director Brown, the firm services approximately 20,000 which are roughly divided equally between retail accounts and chain accounts. Of the retail accounts, only around 1500 receive controlled substances. All SOM activities are conducted at the corporate headquarters. According to staff, the firm's growth is mostly driven by shipping non-controlled items. The firm has five SOM employees who report to the Director and Executive Director of Compliance.

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ANDA provided BuzzeoPDMA Consultants with extensive information and documentation pertaining to corporate interaction with the DEA regarding SOM issues dating to 2007 when ANDA and Watson employees were invited to DEA Headquarters to discuss ANDA's SOM procedures. From 2007 continuing sporadically through this year the DEA has appeared to have an interest in ANDA's SOM program. Although there have not been any major official sanctions, the DEA has conferred with ANDA leadership on multiple occasions. What appeared as "routine" regulatory investigations in Groveport, Ohio and in Weston, Florida, were not closed for long periods of time. Also, in 2012, ANDA opened a new distribution facility in Olive Branch Mississippi. Although the DEA conducted a pre-registration investigation, the DEA did not act on the application for registration until June of this year.

In July of 2010, the Miami Field Division conducted an investigation at the Weston location. In November of 2011, ANDA received a "Letter of Admonition" from the DEA alleging a recordkeeping violation and an SOM issue relating to customer purchases in excess of ANDA's stated thresholds. ANDA responded to the letter.

In September of 2014, the Miami Field Division began an inspection of the Weston location that was continued in May and June of 2015, and concluded on July 31, 2015 with a close out meeting that was attended by Diversion Program Manager Susan Langston and other DEA staff. According to ANDA management, at that meeting, DEA staff represented that ANDA should have been subjected to additional regulatory sanctions in 2011 and also discussed one order at length as being problematic from a DEA point of view. However, the DEA encouraged ANDA to supply a pharmacies with those items required to service legitimate medical conditions and used the Publix pharmacy located inside the Moffitt Cancer Center in Tampa as an example of the type of location that should be receiving controlled substances, implying that no additional due diligence may be required in this case. (BuzzeoPDMA recommends that this pharmacy remain part of a compliant SOM program and with registration verification with each order.)

ANDA is asking BuzzeoPDMA to review their SOM system as an outside party to determine whether there are gaps or areas that could be improved.

SOM REGULATORY FOUNDATION

The regulatory foundation for suspicious order monitoring is contained in the following regulation:

§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious

orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Information contained in the regulations has been embellished by the DEA through communications furnished to registrants in 2006 and 2007. These "SOM letters" establish expectations for greater registrant customer oversight and reporting; however, neither the language of the regulation nor the DEA "SOM letters" provide a specific roadmap for DEA registrants to follow to be assured of compliance with the regulation. In correspondence to registrants dated 12.27.2007, the DEA states that "… the DEA does not approve or otherwise endorse and specific system for reporting suspicious orders."

BuzzeoPDMA Recommends those clients develop their SOM systems to address each of the following elements:

- An aggressive "know your customer" program to be assured that controlled substance products are not being distributed to inappropriate customers or that the firm's products are not improperly distributed by others in their supply chain ("downstream distribution").
- An order entry system that seeks to determine whether orders are of unusual size, of unusual frequency and/or deviate from a normal pattern.
- Procedures to identify and "pend" orders that are possibly suspicious; investigate the "pended" orders, document the investigation of the orders, and report the orders to the DEA if required.
- Implementation of on-site customer reviews as required.
- Development of SOPs that describe the registrant's SOM program, processes and procedures
- A "culture of compliance" that recognizes the drug abuse potential of the products the registrant handles and supports employee actions as necessary for fulfilling SOM regulatory requirements.
- Management and staff regulatory training programs

ANDA "KNOW YOUR CUSTOMER" PROCEDURES

New accounts are identified via ANDA's sales and marketing processes. An account must be open for three months before the account may initiate a request to order controlled substances. ANDA uses a questionnaire to provide background information on all new customers. A sales representative will usually forward the questionnaire to the customer. The questionnaire is four pages long. There is an additional page for the owner to attest to his understanding of the

regulations. The questionnaire and attestation page are common to many found in industry. ANDA also requests three months of dispensing data for the top 100 controlled products and the number of prescriptions written, in addition to any written procedures the prospective customer has in place for dispensing controlled substances.

According to staff, questionnaires are mostly received electronically. ANDA has four employees assigned to SOM compliance activities. All staff workers can access any SOM customer account and work in the account. New questionnaires are assigned to the next available staff worker. It was reported by management that customer "due diligence" activity include checking registrations and licenses, formatting and analyzing prescription data, reviewing distances of patients and physicians from the pharmacy, conducting internet research on the pharmacy and the primary prescribers, reviewing professional board web sites for disciplinary action and physician training or certifications and using "Google Maps" for photographs of the pharmacy and the area.

The process used to investigate these new applications is referred to as the "remedy review" process. As a matter of policy, new accounts may not order methadone or oxycodone and may not order more than 1000 of any controlled substance. An additional review will be required to order methadone or oxycodone and/or to increase the customer's order threshold.

SOM employees report to Regulatory Compliance Director Robert Brown. It was reported that his staff will determine whether to allow a customer to order controlled substances and/or adjust their purchase levels after initially authorized, although the account sales representative will communicate the information to the account. It should be noted that adjusting a purchase level could be interpreted by the DEA as a possible reason for reporting a suspicious order. Director Brown indicated that ANDA will sometimes report an account to the DEA at the time the due diligence "remedy review" is completed. It was also reported that the Compliance Department requests fresh dispensing data every year and a new questionnaire every three years.

Finding and Recommendations

- Threshold based systems should be avoided (see below, "Electronic Analysis of Orders.")
- ***BuzzeoPDMA recommends*** on site "due diligence" visits as a best practice.
- ***BuzzeoPDMA recommends*** that clients discontinue all control substance sales to a customer that has been reported to the DEA

ELECTRONIC ANALYSIS OF ORDERS

ANDA's Electronic SOM model is described in SOP 040. This procedure uses the term "orders of interest" to describe customer orders that are held or "pended" for additional investigative work to determine whether the orders would be considered suspicious (and reported to the DEA as required by the regulations). According to the SOP, the system performs calculations based upon customer historical user averages which are multiplied by a defined factor to establish a basis for pending an order for additional investigation.

Calculations are performed on the customer's average dose per month of a specific chemical family. Calculations are performed on the customer's average dosage unit per order of a specific chemical family. And, calculations are performed on the average dosage units per order by class of trade for a specific chemical family. Calculations are based on a rolling 30 day period. No additional information regarding SOM model attributes is contained in the SOP. However, during interviews with staff, Consultants learned that [redacted] is the factor used to "pend" orders for additional investigation. ANDA could not provide information regarding how the factor of [redacted] was established.

No additional SOM model calculations are performed, since ANDA uses a "threshold" based system and the assigned thresholds will control limits per order. As noted above new customers may not order controlled substances initially. Once approved for ordering controlled substances, the customer may not order more than 1000 of any particular controlled substance. Additional customer examination and approval is required to order oxycodone and methadone. According to Executive Director Michael Cochrane the thresholds were initially set at 5000 per order. This was based upon guidance provided by Michael Mapes and Kyle Wright at the DEA. The threshold was reduced to 1000 after a DEA inspection at the Weston facility in July of 2010. ANDA also reported that additional SOM changes were implemented following this inspection.

Findings and Recommendations

- Threshold based systems are static and may be difficult to defend due to the ongoing interaction of staff in establishing and changing thresholds. ***BuzzeoPDMA recommends*** statistical modeling to develop a more robust electronic order evaluation process. This approach is dynamic, since each order is evaluated against an order entry calculation and the order amount that will "pend" an order for investigation changes. Customers do not know their limits and will not be able to adjust ordering practices to avoid ordering issues with ANDA.

- ***BuzzeoPDMA recommends*** monitoring quantity, frequency and pattern in conjunction with the SOM process as required by the regulations.

- ANDA's SOM electronic ordering calculations are driven by averages and the use of a factor to determine which orders will "pend." ***BuzzeoPDMA recommends*** that ANDA

analyze order entry and "pending" activity based upon customers, including class of trade, to determine what factor (or factors) should be used for their diverse number of customers and the large number of controlled substances available for use by patients. Information gleaned from such an analysis should be documented and incorporated into ANDA's SOM procedures.

- As a secondary supplier, ANDA's customers may place orders sparsely over time. Six months of order history is insufficient to capture reliable customer order patterns. ***BuzzeoPDMA recommends*** using 12 to 18 months of data for SOM modeling. Extrapolating information from customers in the same class of trade may also provide insight for the activities of individuals with the group (e.g. If a pharmacy is purchasing infrequently based upon the individual history, the purchase patterns of the group may be used to compare and/or explain this individual ordering pattern.)

- Consultants further concluded that ANDA should develop better documentation on both the electronic order entry process and the effectiveness of their SOM program in general.

- ***BuzzeoPDMA recommends*** that ANDA validate their SOM computer program. ANDA should further produce "back end" reports to show the total number of controlled substance orders received, the total number held for investigation, the number cleared and the number reported to the DEA. Similar information should be developed to show what reason codes are used to clear orders and how accounts are closed and reported to the DEA.

REVIEW OF ORDERS

Controlled substance orders are pended either because they are in excess of the SOM model calculation ([redacted]) or because they are in excess of the customer's threshold. In both cases the firm uses the "Remedy Review Process" to determine whether the order should be reported to the DEA. This process is also used to determine whether the threshold should be increased and to authorize customers to order oxycodone and methadone. When a controlled substance order is pended, the entire order is pended.

The "Remedy Review Process" was described to Consultants by individual staff members who opened computer screens to show the information on file and then discuss the types of things that they do for various account types in terms of investigating the order and resolving/adjudicating the issue. Information regarding the remedy review process is also described in SOP 045, which was made available to BuzzeoPDMA Consultants prior to the visit.

Investigative procedures as listed in SOP 045 are summarized as follows:

- Check the customer's license information
- Review the customer's history and previous compliance notes

- Determine whether the customer has previously been "cut off"
- Determine whether there is a change of ownership
- Review customer questionnaire
- Conduct research on line
- Review dispensing data from pharmacy
- Review customer business needs

Consultants observed real electronic files that were used to document due diligence activity for new accounts and other types of order adjustments. It appeared through interviews with staff that ANDA's SOM staff used an open ended, inductive reasoning approach to investigating SOM issues. It was reported that the SOM staff has been mostly recruited internally with backgrounds in customer service, purchasing and sales support. Controlled substance diversion and abuse training appeared to be mostly informal; however, ANDA does send employees to conferences and provides training support on a rotating basis. Staff is authorized to request additional dispensing data as required and/or a new "due diligence" questionnaire. Information is scanned into the electronic record. It was also reported that dispensing data may be roughly correlated with sales data to determine whether there is some level of accountability for the drugs ordered and the drugs dispensed.

As previously noted, suspicious orders are reported to the DEA; however, ANDA will frequently report the customer to the DEA. It was further reported that if an order is reported to the DEA the account will no longer be authorized to purchase controlled substances from ANDA. Director Brown indicated that few orders are reported to the DEA. He explained that the firm's due diligence process and ongoing account management was effective and that questionable accounts are more likely closed and/or never authorized to order controlled substances so that the number of orders reported is reduced. ANDA staff also reported that the firm furnishes the DEA with a weekly list of customers who have been denied controlled substances and customers who have been reinstated. This list is submitted electronically to numerous DEA offices with jurisdiction over ANDA facilities. This report has been submitted to the DEA since 2010.

Findings and Recommendations

- ***BuzzeoPDMA recommends*** continued training for staff regarding diversion and drug abuse issues. It was noted, for example, that a Mid-Level Practitioner was identified as one of the most prevalent prescribers in a report, which Consultants felt was unusual. In addition to training sessions sponsored by the DEA, BuzzeoPDMA, and others, ANDA should consider joining the National Association of Drug Diversion Investigators (NADDI) which sponsors local training opportunities and has a "list serve" to share relevant diversion information.

- ***BuzzeoPDMA recommends*** recurring on site due diligence visits as a part of their due diligence process and as a part of the firm's suspicious order clearing process. Although

on site reviews are described as an option for the Regulatory Compliance team in SOP # 045, management indicated that the firm did not conduct on site reviews and no information regarding this procedure surfaced during interviews with staff.

  - The on-site reviews should include the following (not meant to be all inclusive):
    - Patient population
    - Controlled substance prescriptions dispensed
    - Method of payment
    - Prescriber's medical practice and expertise
    - Alternative treatments

- ***BuzzeoPDMA*** also ***recommends*** that ANDA include a separate tab on their weekly reports to the DEA for suspicious orders reported and those registrants who are no longer customers as an additional factor in supporting overall system effectiveness.

ANDA's SOM SUPPORT AND CULTURE OF COMPLIANCE

Consultants determined through interviews with staff and an examination of provided documents that ANDA supports regulatory oversight for the SOM process. As noted throughout, there is a well-defined SOM organization with training and support for SOM review activities.

According to management and staff, the sales staff interacts with customers on a frequent basis and is involved in communicating SOM issues to customer pharmacies, as would be expected. However, the Regulatory Department has the final say on whether an account will be authorized to order controlled substances and/or what the threshold is. ANDA management reported that there are periodic meetings with sales and regulatory; however, it was reported that specific information regarding the investigation of accounts and orders was not shared with the sales representatives.

From a broader perspective, ANDA does have some initiatives in place to foster employee sensitivity to drug abuse issues and the firm's responsibility to sell controlled substances responsibly. The firm does have a "Drug Free Work Place" policy; however, it is included in the firm's Standards of Conduct and not visibly promoted internally. The firm also requires pre-employment and "for cause" drug testing.

ANDA also participates in a program called "It Starts with Me" which was developed by Actavis. This is a program developed to promote drug abuse prevention initiatives through company support and community outreach.

As can be surmised in the program's title, "It Starts with Me" encourages employees to recognize the importance of drug abuse prevention and control regulations and further encourages employees to work in the community through ongoing corporate relationships with key community educators and stakeholders.

Program Highlights as noted in information provided to Consultants are listed as follows:

- The relationship between diversion prevention and successful operations and the public interest
- Workplace behaviors that promote the secure handling of controlled substances throughout the product lifecycle
- One's personal obligations under the compliance program
- Compliance with regulatory requirements

Director Brown also furnished follow up information after the on-site review regarding ANDA's initiatives to train pharmacists on controlled substance issues. ANDA has provided a grant to develop a course for pharmacists with "continuing education credits." The goal of the course as noted in the provided informational materials is to "provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing." Director Brown indicated that 3000 pharmacists have taken the course. It was also noted in the materials provided that the program will expire in December of 2015.

Findings and Recommendations

- ***BuzzeoPDMA recommends*** that ANDA institute a policy of random drug testing for all employees.

- ***BuzzeoPDMA recommends*** that ANDA extend the pharmacist education program past the current expiration date.

QUALIFICATIONS

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations, and our experience with them. Many of the requirements of the CSA and regulations thereunder are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations.